

Application No. 10/678,751  
Reply to Office Action Dated June 16, 2005  
Amendment Dated September 16, 2005

## REMARKS

Claims 51-113 were pending in the present application. The Examiner has made the previous restriction requirement final and thus has withdrawn from consideration claims 63-76, 85-88 and 91-113 as directed to non-elected subject matter. By this Amendment, Applicants have cancelled withdrawn 63-76, 85-88 and 91-113 without prejudice to the right to present the subject matter of these claims in a future continuation or divisional application. Applicants have amended claim 77 to recite that the matrix is a "biocompatible chitosan matrix." The present Amendment does not introduce any new matter, and thus, its entry is requested. Upon entry of the present Amendment, claims 51-62, 77-84, and 89-90 will be pending and under examination.

### **The June 16, 2005 Office Action**

#### Examiner's rejections under 35 U.S.C. §102

Claims 51-55 were rejected under 35 U.S.C. §102(b) as being anticipated by Thompson (U.S. Pat. No. 5,531,735). According to the Examiner, Thompson discloses medical devices fabricated from amine functionalized polymers such as chitosan and alginic acid. Thompson indicates that the matrix polymers forming the medical devices can be either porous or relatively non-porous materials (col. 5, lines 51-55), and that lactic and glycolic acids can be present in the matrix.

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In response, Applicants respectfully traverse the rejection. Applicants point out that in contrast to the present invention, wherein the hydroxy carboxylic acid is used to prepare the non-porous chitosan matrix, the hydroxy carboxylic acid according to Thompson acts to initiate decomposition of the matrix polymer when contacted therewith. Moreover, and perhaps more significantly, however, is the fact that according to column 5, lines 51-52 of the specification, Thompson only discloses matrix polymers which are "*either porous materials or relatively non-porous materials*". (Emphasis added). This feature exhibits a clear difference between the cited document and the subject matter of the present application. Therefore, Thompson does not meet the limitations of claims 51-55 and thus does not anticipate Applicants' claims. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Claims 77-83 (directed to biocompatible matrices having anisotropic structures) were rejected under 35 U.S.C. §102(b) as being anticipated by Li (U.S. Pat. No. 6,090,996). According to the Examiner, Li discloses an implant comprising a porous matrix sheet that is made of biocompatible and bioresorbable biopolymeric material, with the sheet comprising collagen and molecules such as chitosan, growth factors, polynucleotides, and combinations thereof. The Examiner notes that lactic acid is used in the formation of the collagen fibers.

In response, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicants have amended claim 77 to clarify that the claimed matrix is a "biocompatible chitosan matrix." Applicants believe that this clarification overcomes the Examiner's rejection based on Li. Li refers to an implant

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comprising a porous matrix sheet made of a biocompatible and bioresorbable biopolymeric material. The matrix sheet is typically prepared of Type I collagen and may additionally comprise bioactive molecules, such as hyaluronic acid or chitosan.

However, Li does not describe the chitosan matrix of the present invention. Rather, Li refers to an implant matrix, i.e. a collagen matrix, which may optionally contain bioactive molecules such as chitosan if the matrix is intended to function as a delivery vehicle for bioactive molecules. Li does not disclose a "biocompatible chitosan matrix." In the Applicants' claims, as amended, chitosan is not present in the matrix in only a minor amount which is the case with Li, but rather forms the matrix itself. Therefore, Li does not anticipate Applicants' claims, as amended. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §102 based on Li.

#### Examiner's Rejection Under 35 U.S.C. §103

Claims 51-62, 77-84, 89, and 90 were rejected under 35 U.S.C. §103 as being obvious over Bakker, et al. (U.S. Pat. No. 5,508,036). According to the Examiner, Bakker discloses a medical device that is a composite of first and second layers, each comprising biodegradable or bioerodable polymers that may be the same or different. Moreover, according to the Examiner, Bakker teaches structures in which one layer is porous and the other is non-porous. The Examiner has asserted that the claims are therefore rendered obvious over the Bakker patent.

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In response, Applicants respectfully traverse the Examiner's rejection. Bakker does not in fact provide an indication that the first non-porous layer and the second porous layer, respectively, may be a chitosan matrix. In contrast, according to column 12, lines 20-50 of the reference, chitosan is only disclosed as an adhesive material capable of forming an adherence layer. Replacing the porous second layer, the adherence layer is intended to adhere to tissue or bone such that the device prevents the binding of tissue to tissue or tissue to bone. Accordingly, Bakker neither provides an indication that chitosan may be suitable for preparing the non-porous first layer and/or the porous second layer as suggested by the present invention, nor does it make a suggestion on how to prepare such chitosan matrices. As Bakker also does not provide any indication that application and non-application, respectively, of freeze-drying may determine whether a porous or a non-porous matrix is obtained, one of ordinary skill in the art would not have had any motivation to use the teaching of Bakker in order to prepare the chitosan matrices claimed by the present invention. Therefore, Bakker does not render obvious Applicants' claimed invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103.

In view of the above remarks and amendments, Applicants believe that all of the Examiner's rejections set forth in the June 16, 2005 Office Action have been fully overcome and that the present application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

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No fee is believed due in connection with the filing of this Amendment. However, if any fee is deemed necessary, authorization is hereby given to charge such fee, or credit any overpayment, to deposit account 02-2135.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Skacel', written over a horizontal line.

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